Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1-80 (Canceled).

81. (New) A method for sterilizing a biological material that is sensitive to radiation, said method comprising:

(i) adding to said biological material:

(a) at least one dipeptide stabilizer in an amount effective to protect said biological material from said radiation; or

(b) a mixture of two or more stabilizers in an amount effective to protect said biological material from said radiation, wherein said mixture of two or more stabilizers is selected from the group consisting of: mixtures of ascorbic acid, or a salt or ester thereof, and uric acid, or a salt or ester thereof; mixtures of ascorbic acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; and mixtures of uric acid, or a salt or ester thereof, lipoic acid, sodium formaldehyde sulfoxylate, gallic acid or a derivative thereof, propyl gallate and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; and

(ii) irradiating said biological material with a suitable radiation at an effective rate for a time effective to sterilize said biological material.

82. (New) The method according to claim 81, wherein said dipeptide stabilizer is

selected from the group consisting of glycyl-glycine (Gly-Gly), carnosine and anserine.

83. (New) The method according to claim 81, further comprising applying to said biological material at least one stabilizing process selected from the group consisting of

(a) reducing the residual solvent content of said biological material; and

(b) reducing the temperature of said biological material,

wherein, said mixture of two or more stabilizers or said at least one dipeptide stabilizer, and said at least one stabilizing process are together effective to protect said biological material from said radiation.

84. (New) The method according to claim 83, comprising applying to said biological material both of said stabilizing processes.

85. (New) A method for sterilizing a biological material that is sensitive to radiation, said method comprising irradiating said biological material with radiation for a time effective to sterilize said biological material at a rate effective to sterilize said biological material and to protect said biological material from said radiation, wherein at least one sensitizer is added to said biological material prior to said step of irradiating said biological material and said at least one sensitizer comprises at least one ligand.

86. (New) The method according to claim 85, further comprising applying to said biological material prior to irradiating at least one stabilizing process selected from the group consisting of:

(a) reducing the residual solvent content of said biological material;

(b) reducing the temperature of said biological material; and

(c) adding at least one stabilizer to said biological material,

wherein said at least one stabilizing process and said rate of irradiation are together effective to protect said biological material from said radiation.

87. (New) The method according to claim 86, comprising applying to said biological material at least two stabilizing processes, wherein said at least two stabilizing processes and said rate of irradiation are together effective to protect said biological material from said radiation and further wherein said at least two stabilizing processes may be performed in any order.

88. (New) The method according to claims 83 or 86, wherein said solvent is water.

89. (New) The method according to claims 83 or 86, wherein said residual solvent content is reduced by the addition of an organic solvent.

90. (New) The method according to claims 83 or 86, wherein said solvent is an organic solvent.

91. (New) The method according to claims 81 or 85, wherein said effective rate is not more than 3.0 kGy/hour.

92. (New) The method according to claims 81 or 85, wherein said effective rate is not more than 2.0 kGy/hr.

93. (New) The method according to claims 81 or 85, wherein said effective rate is not more than 1.0 kGy/hr.

94. (New) The method according to claims 81 or 85, wherein said effective rate is not more than 0.3 kGy/hr.

95. (New) The method according to claims 81 or 85, wherein said effective rate is more than 3.0 kGy/hour.

96. (New) The method according to claims 81 or 85, wherein said effective rate is at

least 6.0 kGy/hour.

97. (New) The method according to claims 81 or 85, wherein said effective rate is at least 18.0 kGy/hour.

98. (New) The method according to claims 81 or 85, wherein said effective rate is at least 30.0 kGy/hour.

99. (New) The method according to claims 81 or 85, wherein said effective rate is at least 45 kGy/hour.

100. (New) The method according to claims 81 or 85, wherein said biological material is maintained in a low oxygen atmosphere.

101. (New) The method according to claims 81 or 85, wherein said biological material is maintained in an atmosphere comprising at least one noble gas.

102. (New) The method according to claim 101, wherein said noble gas is argon.

103. (New) The method according to claims 81 or 85, wherein said biological material is maintained in a vacuum.

104. (New) The method according to claims 83 or 86, wherein said residual solvent content is reduced by a method selected from the group consisting of lyophilization, drying, concentration, addition of solute, evaporation, chemical extraction, spray-drying, and vitrification.

105. (New) The method according to claims 83 or 86, wherein said residual solvent content is less than 15%.

106. (New) The method according to claims 83 or 86, wherein said residual solvent

content is less than 10%.

107. (New) The method according to claims 83 or 86, wherein said residual solvent content is less than 3%.

108. (New) The method according to claims 83 or 86, wherein said residual solvent content is less than 2%.

109. (New) The method according to claims 83 or 86, wherein said residual solvent content is less than 1%.

110. (New) The method according to claims 83 or 86, wherein said residual solvent content is less than 0.5%.

111. (New) The method according to claims 83 or 86, wherein said residual solvent content is less than 0.08%.

112. (New) The method according to claims 81 or 85, wherein said biological material contains at least one other biological contaminant or pathogen selected from the group consisting of viruses, bacteria and fungi.

113. (New) The method according to claims 81 or 86, wherein said at least one stabilizer reduces damage due to reactive oxygen species.

114. (New) The method according to claims 81 or 85, wherein said radiation is corpuscular radiation or electromagnetic radiation, or a mixture thereof.

115. (New) The method according to claim 114, wherein said electromagnetic radiation is selected from the group consisting of radio waves, microwaves, visible and invisible light, ultraviolet light, x-ray radiation, gamma radiation and combinations thereof.

116. (New) The method according to claims 81 or 85, wherein said radiation is gamma radiation.

117. (New) The method according to claims 81 or 85, wherein said radiation is e-beam radiation.

118. (New) The method according to claims 81 or 85, wherein said radiation is visible light.

119. (New) The method according to claims 81 or 85, wherein said radiation is ultraviolet light.

120. (New) The method according to claims 81 or 85, wherein said radiation is x-ray radiation.

121. (New) The method according to claims 81 or 85, wherein said radiation is polychromatic visible light.

122. (New) The method according to claims 81 or 85, wherein said radiation is infrared.

123. (New) The method according to claims 81 or 85, wherein said radiation is a combination of one or more wavelengths of visible and ultraviolet light.

124. (New) The method according to claims 81 or 85, wherein said irradiation is conducted at ambient temperature.

125. (New) The method according to claims 81 or 85, wherein said irradiating is conducted at a temperature below ambient temperature.

126. (New) The method according to claims 81 or 85, wherein said irradiating is

conducted below the freezing point of said biological material.

127. (New) The method according to claims 81 or 85, wherein said irradiating is conducted below the eutectic point of said biological material.

128. (New) The method according to claims 81 or 85, wherein said irradiating is conducted at a temperature above ambient temperature.

129. (New) The method according to claim 85, wherein said ligand is a metal ion.

130. (New) The method according to claim 129, wherein said metal ion is a copper ion.

131. (New) A composition comprising at least one biological material and at least one stabilizer in an amount effective to preserve said biological material for its intended use following sterilization with radiation, wherein said biological material is glassy or vitrified.

132. (New) A composition comprising at least one biological material, wherein the residual solvent content of said biological material is at a level effective to preserve said biological material for its intended use following sterilization with radiation, wherein said biological material is glassy or vitrified.

133. (New) The composition of claim 132, wherein said residual solvent content is less than 15%.

134. (New) The composition of claim 132, wherein said residual solvent content is less than 10%.

135. (New) The composition of claim 132, wherein said residual solvent content is less than 5%.

136. (New) The composition of claim 132, wherein said residual solvent content is less than 2%.

137. (New) The composition of claim 132, wherein said residual solvent content is less than 1%.

138. (New) The composition of claim 132, wherein said residual solvent content is less than 0.5%.

139. (New) The composition of claim 132, wherein said residual solvent content is less than 0.08%.

140. (New) The composition of claims 131 or 132, wherein said biological material is selected from the group consisting of monoclonal immunoglobulins, polyclonal immunoglobulins, glycosidases, sulfatases, urokinase and Factor VIII.

141. (New) The composition of claim 132, wherein the concentration of said biological material is at least 0.5%.

142. (New) The composition of claim 132, wherein the concentration of said biological material is at least 1%.

143. (New) The composition of claim 132, wherein the concentration of said biological material is at least 5%.

144. (New) The composition of claim 132, wherein the concentration of said biological material is at least 10%.

145. (New) The composition of claim 132, wherein the concentration of said biological material is at least 15%.

146. (New) The composition of claim 132, wherein the concentration of said biological material is at least 20%.

147. (New) The composition of claim 132, wherein the concentration of said biological material is at least 25%.

148. (New) The composition of claim 132, wherein the concentration of said biological material is at least 50%.

149. (New) A method for sterilizing a biological material that is sensitive to radiation, said method comprising irradiating said biological material with radiation for a time effective to sterilize said biological material at a rate effective to sterilize said biological material and to protect said biological material from said radiation, wherein said effective rate is not constant and comprises a rate of between 0.1kGy/hr to 3.0kGy/hr for at least a portion of said period of time and a rate of at least 6.0kGy/hr for at least another portion of said period of time.

150. (New) The method according to claim 149, further comprising applying to said biological material prior to irradiating at least one stabilizing process selected from the group consisting of:

(a) reducing the residual solvent content of said biological material;

(b) reducing the temperature of said biological material; and

(c) adding at least one stabilizer to said biological material,

wherein said at least one stabilizing process and said rate of irradiation are together effective to protect said biological material from said radiation.

151. (New) The method according to claim 150, comprising applying to said biological material at least two stabilizing processes, wherein said at least two stabilizing processes and said rate of irradiation are together effective to protect said biological material from said radiation and further wherein said at least two stabilizing processes may be

performed in any order.

152. (New) The method according to claim 149, wherein said effective dose rate comprises a rate between 0.25 kGy/hr to 2.0 kGy/hr for at least a portion of said period of time and a rate of at least 6.0 kGy/hr for at least another portion of said period of time.

153. (New) The method according to claim 149, wherein said effective dose rate comprises a rate between 0.5 kGy/hr to 1.5 kGy/hr for at least a portion of said period of time and a rate of at least 6.0 kGy/hr for at least another portion of said period of time.

154. (New) The method according to claim 149, wherein said effective dose rate comprises a rate between 0.5 kGy/hr to 1.0 kGy/hr for at least a portion of said period of time and a rate of at least 6.0 kGy/hr for at least another portion of said period of time.

155. (New) The method according to claim 150, wherein said solvent is water.

156. (New) The method according to claim 150, wherein said residual solvent content is reduced by the addition of an organic solvent.

157. (New) The method according to claim 150, wherein said solvent is an organic solvent.

158. (New) The method according to claim 150, wherein said biological material is suspended in an organic solvent following reduction of said residual solvent content.

159. (New) The method according to claim 149, wherein said effective rate further comprises a rate of at least 18.0 kGy/hour for at least another portion of said period of time.

160. (New) The method according to claim 149, wherein said effective rate further comprises a rate of at least 30.0 kGy/hour for at least another portion of said period of time.

161. (New) The method according to claim 149, wherein said effective rate further comprises a rate of at least 45 kGy/hour for at least another portion of said period of time.

162. (New) The method according to claim 149, wherein said biological material is maintained in a low oxygen atmosphere.

163. (New) The method according to claim 149, wherein said biological material is maintained in an atmosphere comprising at least one noble gas.

164. (New) The method according to claim 163, wherein said noble gas is argon.

165. (New) The method according to claim 149, wherein said biological material is maintained in a vacuum.

166. (New) The method according to claim 150, wherein said residual solvent content is reduced by a method selected from the group consisting of lyophilization, drying, concentration, addition of solute, evaporation, chemical extraction, spray-drying, and vitrification.

167. (New) The method according to claim 150, wherein said residual solvent content is less than 15%.

168. (New) The method according to claim 150, wherein said residual solvent content is less than 10%.

169. (New) The method according to claim 150, wherein said residual solvent content is less than 3%.

170. (New) The method according to claim 150, wherein said residual solvent content is less than 2%.

171. (New) The method according to claim 150, wherein said residual solvent content is less than 1%.

172. (New) The method according to claim 150, wherein said residual solvent content is less than 0.5%.

173. (New) The method according to claim 150, wherein said residual solvent content is less than 0.08%.

174. (New) The method according to claim 149, wherein at least one sensitizer is added to said biological material prior to said step of irradiating said biological material.

175. (New) The method according to claim 149, wherein said biological material contains at least one other biological contaminant or pathogen selected from the group consisting of viruses, bacteria and fungi.

176. (New) The method according to claim 150, wherein said at least one stabilizer is an antioxidant.

177. (New) The method according to claim 150, wherein said at least one stabilizer is a free radical scavenger.

178. (New) The method according to claim 150, wherein said at least one stabilizer is a combination stabilizer.

179. (New) The method according to claim 150, wherein said at least one stabilizer is a ligand.

180. (New) The method according to claim 179, wherein said ligand is heparin.

181. (New) The method according to claim 150, wherein said at least one stabilizer

reduces damage due to reactive oxygen species.

182. (New) The method according to claim 150, wherein said at least one stabilizer is selected from the group consisting of: ascorbic acid or a salt or ester thereof; glutathione; 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; uric acid or a salt or ester thereof; methionine; histidine; N-acetyl cysteine; lipoic acid; sodium formaldehyde sulfoxylate; gallic acid or a derivative thereof; propyl gallate; extraneous proteins; and mixtures of two or more thereof.

183. (New) The method according to claim 182, wherein said mixtures of two or more additional stabilizers are selected from the group consisting of: mixtures of ascorbic acid, or a salt or ester thereof, and uric acid, or a salt or ester thereof; mixtures of ascorbic acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; mixtures of ascorbic acid, or a salt or ester thereof, uric acid, or a salt or ester thereof, and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; and mixtures of uric acid, or a salt or ester thereof, lipoic acid, sodium formaldehyde sulfoxylate, gallic acid or a derivative thereof, propyl gallate and 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid.

184. (New) The method according to claim 150, wherein said at least one stabilizer is a dipeptide stabilizer.

185. (New) The method according to claim 184, wherein said dipeptide stabilizer is selected from the group consisting of glycyl-glycine (Gly-Gly), carnosine and anserine.

186. (New) The method according to claim 149, wherein said radiation is corpuscular radiation or electromagnetic radiation, or a mixture thereof.

187. (New) The method according to claim 186, wherein said electromagnetic radiation is selected from the group consisting of radio waves, microwaves, visible and invisible light, ultraviolet light, x-ray radiation, gamma radiation and combinations thereof.

188. (New) The method according to claim 149, wherein said radiation is gamma radiation.

189. (New) The method according to claim 149, wherein said radiation is e-beam radiation.

190. (New) The method according to claim 149, wherein said radiation is visible light.

191. (New) The method according to claim 149, wherein said radiation is ultraviolet light.

192. (New) The method according to claim 149, wherein said radiation is x-ray radiation.

193. (New) The method according to claim 149, wherein said radiation is polychromatic visible light.

194. (New) The method according to claim 149, wherein said radiation is infrared.

195. (New) The method according to claim 149, wherein said radiation is a combination of one or more wavelengths of visible and ultraviolet light.

196. (New) The method according to claim 149, wherein said irradiation is conducted at ambient temperature.

197. (New) The method according to claim 149, wherein said irradiation is conducted at a temperature below ambient temperature.

198. (New) The method according to claim 149, wherein said irradiation is conducted below the freezing point of said biological material.

199. (New) The method according to claim 149, wherein said irradiation is conducted

below the eutectic point of said biological material.

200. (New) The method according to claim 149, wherein said irradiation is conducted at a temperature above ambient temperature.

201. (New) The method according to claim 174, wherein said sensitizer is a ligand.

202. (New) The method according to claim 201, wherein said ligand is a metal ion.

203. (New) The method according to claim 202, wherein said metal ion is a copper ion.

204. (New) The composition according to claims 131 or 132, wherein said biological material is selected from the group consisting of: cells, tissues, blood, blood components, proteins, enzymes, immunoglobulins, botanicals, food, ligaments, tendons, nerves, bone, demineralized bone matrix, grafts, joints, femurs, femoral heads, teeth, skin grafts, bone marrow, heart valves, cartilage, corneas, arteries, veins, meat, organs, limbs, digits, lipids, carbohydrates, collagen, chitin, stem cells, islet of Langerhans cells, genetically altered cells, red blood cells, white blood cells, proteinaceous material and combinations thereof.

205. (New) The composition according to claim 204, wherein said blood components are selected from the group consisting of cellular blood components, blood proteins, liquid blood components and combinations thereof.

206. (New) The composition according to claims 131 or 132, wherein said biological material is whole or processed.

207. (New) The composition according to claim 204, wherein said collagen is

selected from the group consisting of native collagen, afibrillar collagen, atelomeric collagen, soluble collagen and insoluble collagen.

208. (New) The composition according to claim 204, wherein said biological material comprises a protein or peptide produced from cell culture.

209. (New) The composition according to claims 131 or 132, wherein said biological material is selected from the group consisting of hearts, livers, lungs, kidneys, intestines and pancreas.

210. (New) The composition according to claim 131, wherein said at least one stabilizer is selected from the group consisting of polyhydric alcohols, trehalose, mannitol, DMSO, glyceroland combinations thereof.

211. (New) The composition according to claim 131, wherein said at least one stabilizer comprises trehalose.

212. (New) The composition according to claim 131, wherein said at least one stabilizer comprises a polyhydric alcohol.

213. (New) The composition according to claim 131, wherein said at least one stabilizer comprises glycerol.

214. (New) The composition according to claim 131, wherein said at least one stabilizer comprises mannitol.

215. (New) The composition according to claim 131, wherein said at least one

stabilizer comprises DMSO.

216. (New) The composition according to claims 131 or 132, wherein said biological material is human.

217. (New) The composition according to claims 131 or 132, wherein said biological material is mammalian.

218. (New) The composition according to claims 131 or 132, wherein said biological material is bovine.

219. (New) The composition according to claims 131 or 132, wherein said biological material is equine.

220. (New) The composition according to claims 131 or 132, wherein said biological material is porcine.

221. (New) The composition according to claims 131 or 132, wherein said biological material is transgenic or recombinant.

222. (New) The composition according to claim 221, wherein said biological material is milk.

223. (New) The composition according to claims 131 or 132, wherein said biological material is milk, collagen, plasma or serum.

224. (New) The composition according to claims 131 or 132, wherein said biological material is selected from the group consisting of ligaments, tendons, nerves, bone, teeth, bone marrow, skin grafts, cartilage, corneas, arteries, veins and organs for transplantation.

225. (New) The composition according to claims 131 or 132, wherein said biological material is tissue.

226. (New) The composition according to claim 225, wherein said tissue is selected from the group consisting of bone, grafts, joints, femurs, femoral heads, heart valves, ligaments, hearts, livers, lungs, kidneys, intestines, pancreas, limbs, digits and demineralized bone matrix.

227. (New) The composition according to claims 131 or 132, wherein said biological material is bovine serum.

228. (New) The composition according to claim 227, wherein said biological material is fetal bovine serum.

229. (New) The method according to claims 81, 85, or 149, wherein said biological material is selected from the group consisting of: cells, tissues, blood, blood components, proteins, enzymes, immunoglobulins, botanicals, food, ligaments, tendons, nerves, bone, demineralized bone matrix, grafts, joints, femurs, femoral heads, teeth, skin grafts, bone marrow, heart valves, cartilage, corneas, arteries, veins, meat, organs, limbs, digits, lipids, carbohydrates, collagen, chitin, stem cells, islet of Langerhans cells, genetically altered cells, red blood cells, white blood cells, proteinaceous material and combinations thereof.

230. (New) The method according to claim 229, wherein said blood components are selected from the group consisting of cellular blood components, blood proteins, liquid

blood components and combinations thereof.

231. (New) The method according to claims 81, 85 or 149, wherein said biological material is whole or processed.

232. (New) The method according to claim 229, wherein said collagen is selected from the group consisting of native collagen, afibrillar collagen, atelomeric collagen, soluble collagen and insoluble collagen.

233. (New) The method according to claim 229, wherein said biological material comprises a protein or peptide produced from cell culture.

234. (New) The method according to claims 81, 85, or 149, wherein said biological material is selected from the group consisting of hearts, livers, lungs, kidneys, intestines and pancreas.

235. (New) The method according to claim 150, wherein said at least one stabilizer is selected from the group consisting of polyhydric alcohols, trehalose, mannitol, DMSO, glycerol and combinations thereof.

236. (New) The method according to claim 150, wherein said at least one stabilizer comprises trehalose.

237. (New) The method according to claim 150, wherein said at least one stabilizer is a polydyric alcohol.

238. (New) The method according to claim 150, wherein said at least one stabilizer comprises glycerol.

239. (New) The method according to claim 150, wherein said at least one stabilizer comprises mannitol.

240. (New) The method according to claim 150, wherein said at least one stabilizer comprises DMSO.

241. (New) The method according to claims 81, 85, or 149, wherein said biological material is human.

242. (New) The method according to claims 81, 85, or 149, wherein said biological material is mammalian.

243. (New) The method according to claims 81, 85, or 149, wherein said biological material is bovine.

244. (New) The composition according to claims 81, 85, or 149, wherein said biological material is equine.

245. (New) The composition according to claims 81, 85, or 149, wherein said biological material is porcine.

246. (New) The method according to claims 81, 85, or 149, wherein said biological material is transgenic or recombinant.

247. (New) The method according to claim 246, wherein said biological material is milk.

248. (New) The method according to claims 81, 85, or 149, wherein said biological material is milk, collagen, plasma or serum.

249. (New) The method according to claims 81, 85 or 149, wherein said biological material is selected from the group consisting of ligaments, tendons, nerves, bone, teeth, bone marrow, skin grafts, cartilage, corneas, arteries, veins and organs for transplantation.

250. (New) The method according to claims 81, 85 or 149, wherein said biological material is tissue.

251. (New) The method according to claim 250, wherein said tissue is selected from the group consisting of bone, grafts, joints, femurs, femoral heads, heart valves, ligaments, hearts, livers, lungs, kidneys, intestines, pancreas, limbs, digits and demineralized bone matrix.

252. (New) The method according to claim 175, wherein said method results in a decrease in the D_{37} value of said at least one biological contaminant or pathogen without a concomitant decrease in the D_{37} value of said biological material.

253. (New) The method according to claim 175, wherein said method results in a decrease in the D_{37} value of said at least one biological contaminant or pathogen and a concomitant increase in the D_{37} value of said biological material.

254. (New) The method according to claims 81, 85, 149, or 175, wherein said

method results in an increase in the D_{37} value of said biological material.

255. (New) The method according to claim 175, wherein said method results in an at least 1 log reduction in the level of said biological contaminant or pathogen.

256. (New) The method according to claim 175, wherein said method results in an at least 2 log reduction in the level of said biological contaminant or pathogen.

257. (New) The method according to claim 175, wherein said method results in an at least 3 log reduction in the level of said biological contaminant or pathogen.

258. (New) The method according to claim 175, wherein said method results in an at least 4 log reduction in the level of said biological contaminant or pathogen.

259. (New) The method according to claim 175, wherein said method results in an at least 4.5 log reduction in the level of said biological contaminant or pathogen.

260. (New) The method according to claims 81, 85 or 149, wherein said biological material is bovine serum.

261. (New) The method according to claim 260, wherein said bovine serum is fetal bovine serum.

262. (New) The method according to claim 149, further comprising adding to said biological material a biologically compatible buffered solution.

263. (New) The method according to claim 262, wherein said biologically

compatible buffered solution has a pH of between 4 and 8.5.